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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,296	08/27/2001	Sithian Pandian	MBM1270	7256
7590	08/02/2004		EXAMINER	
Lisa A. Haile Gray, Cary, Ware & Freidenrich 4365 Executive Drive, Suite 1100 San Diego, CA 92121			FORMAN, BETTY J	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 08/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

<b>Office Action Summary</b>	<b>Application No.</b> 09/940,296	<b>Applicant(s)</b> PANDIAN ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 13-29 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 2 July 2004 in which claims 1 and 2 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 2 February 2004 are withdrawn in view of the amendments. The previous Office Action indicated that Claims 25-29 are free of the prior art and in condition for allowance. However, upon further review and new grounds for rejection, the claims are not deemed allowable.

This Application has been transferred to a new examiner. Please address future correspondence to BJ Forman, Art Unit:1634.

New grounds for rejection are discussed.

Claims 13-14 are withdrawn from consideration.

Claims 1-4 and 25-29 are under prosecution.

### ***Specification***

2. The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 25-26 and 27-28 are rejected under 35 U.S.C. 102(e) as anticipated by Urdea (U.S. Patent No. 5,656,731, filed 1 July 1993).

Regarding Claim 1, Urdea discloses an amplification probe comprising at least two nucleic acid sequences (i.e. A-B and C) wherein B includes a sequence complementary to a sequence on a primary probe and a sequence complementary to a nucleic acid target (i.e. A-to-a' region of the capture probe as illustrated in Fig. 2-2 and the promoter sequence, B) (Column 6, lines 22-48) and a second region including more than two sequence units of more than one type i.e. Urdea teaches the probe comprises 3-50 (more than 2) sequence units wherein the sequence units are different (Column 8, lines 12-25). The term "labellable" is a recitation of intended use, however, Urdea teaches the sequence units are labellable via hybridization with labeled probes (Column 15, lines 45-54).

The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding Claim 2, Urdea discloses the number of sequence units ranges from three to fifty (Column 8, lines 12-20).

Regarding Claim 3, Urdea discloses the probes wherein each sequence unit comprising a nucleotide sequence hybridizable to a complementary sequence on a probe wherein the label is covalently attached to the probe (Column 15 lines 47-54 and Column 16, line 51-Column 17, line 3).

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It is noted that the recitation "hybridizable to a complementary sequence on a labelling probe" is a recitation of intended use which does not define or limit the probe. It is further noted that the recitation "said labelling probe covalently attached to a detectable chemical label" does not define or describe the claimed probe. While Urdea teaches the intended uses as recited, it is because Urdea teaches the claimed structural limitations of the probe, that they anticipate the claimed probe.

Regarding Claim 4, Urdea discloses the sequence units of between 16 and 100 nucleotides (Column 8, lines 18-20).

Regarding Claims 25 and 27, Urdea discloses a system/kit comprising a nucleic acid probe comprising a sequence complementary to the sequence to be detected i.e. capture probe (Fig. 3), amplification probe comprising at least two nucleic acid sequences (i.e. A-B and C) wherein B includes a sequence complementary to a sequence on a primary probe and a sequence complementary to a nucleic acid target (i.e. A-to-a' region of the capture probe as illustrated in Fig. 2-2 and the promoter sequence, B) (Column 6, lines 22-48) and a second region including more a plurality of sequence units i.e. Urdea teaches the probe comprises 3-50 (more than 2) sequence units wherein the sequence units are different (Column 8, lines 12-25) and wherein the label is covalently attached to the probe (Column 15 lines 47-54 and Column 16, line 51-Column 17, line 3 and Column 18, lines 10-26) and wherein the system/kit further comprises an antibody capable of binding to the hybrids (Column 4, lines 24-35).

Regarding Claim 26 and 28, Urdea discloses the system/kit further comprises hybridization buffers and wash solution (Column 18, lines 23-25) which they define as including salts (Column 15, lines 13-45).

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***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Urdea (U.S. Patent No. 5,656,731, filed 1 July 1993).

Regarding Claim 29, Urdea discloses a system/kit comprising a nucleic acid probe comprising a sequence complementary to the sequence to be detected i.e. capture probe (Fig. 3), amplification probe comprising at least two nucleic acid sequences (i.e. A-B and C) wherein B includes a sequence complementary to a sequence on a primary probe and a sequence complementary to a nucleic acid target (i.e. A-to-a' region of the capture probe as illustrated in Fig. 2-2 and the promoter sequence, B) (Column 6, lines 22-48) and a second region including more a plurality of sequence units i.e. Urdea teaches the probe comprises 3-50 (more than 2) sequence units wherein the sequence units are different (Column 8, lines 12-25) and wherein the label is covalently attached to the probe (Column 15 lines 47-54 and Column 16, line 51-Column 17, line 3 and Column 18, lines 10-26) and wherein the system/kit further comprises an antibody capable of binding to the hybrids (Column 4, lines 24-35).

Urdea further teaches their probes are useful for detecting known targets in foods (Column 13, lines 45-51) but they do not specifically teach detecting E. coli. However, E.coli are well known as being in foods wherein the detection of E.coli is of great important. Hence, the teaching of Urdea clearly suggests using the probes and kits for detecting E.coli. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probes and kits of Urdea as a diagnostic kit for the detection of E.coli based on the clear suggestion to do so.

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### **Conclusion**

7. No claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

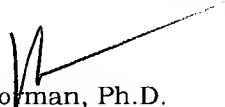
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
July 30, 2004